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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/183,789	10/30/1998	VALERIE MARTELANGE	L0461/7047	3523

7590 11/29/2004

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/183,789	MARTELANGE ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,18,19,40,41,43 and 50-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1, 18, 19, 40, 41, 43 and 50-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendments and Arguments

1. Claims 1, 8, 18, 19, 40, 41, 43 and 50-59 are pending.
Claims 1, 40, 41, 50-56 and 59 have been amended.
Claims 9 and 60 have been cancelled.
Claims 1, 8, 18, 19, 40, 41, 43 and 50-59 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 102

3. The rejection of claims 9 and 60 under 35 U.S.C. 102(b) as being anticipated by 1997/1998 Stratagene catalog (page 118, 1997/1998) are moot in view of the cancellation of the claims.
4. The rejection of claims 18, 19, 50 and 59 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,880,102 (filed January 17, 1995) is withdrawn in light of the amendments to the claims. Claim 9 has been cancelled.

Maintained Grounds of Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1, 18, 19, 40, 50 and 59 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Claims 9 and 60 have been cancelled.

Applicants' traversal of the instant rejection includes a summary of each claim in order to obviate the rejection. Applicants assert that with the amending of claims 1 and 40 the rejection should be withdrawn. Applicants also assert that the disclosure of SEQ ID NO: 38 and SEQ ID NO: 43 coupled with the teachings provided in the specification one of ordinary skill in the art would readily recognize that Applicants were in possession of the claimed invention at the time of filing. These points of view and arguments have been carefully considered, but found unpersuasive.

Applicants' claims embrace complements of nucleic acid molecules that encode polypeptides, SEQ ID NO: 39 or 44 and antisense nucleic acids which bind nucleic acid molecules SEQ ID NO: 38 and SEQ ID NO: 43. Applicants continue not to be in possession of a plethora of sequences that have not been identified or characterized and are regarded as a complement. Applicants are not possession of antisense nucleic acids, which merely bind to sequences 38 and 39. Similarly, these molecules have not evidenced in the specification. These claims that relate to antisense do not set forth a function. The only requirement for any of these nucleic molecules is that they must bind to target sequences. There are an unlimited number of sequences that meet the broad scope of the claims. None of these nucleic acid molecules that simply bind to defined

sequences and undefined complements have been adequately described to convey to one of ordinary skill in the art that Applicants were in possession of the entire genus.

Applicants have express possession of only the disclosed SEQ ID NO: 38, 39, 43 and 44 and not uncharacterized and undefined complements, which comprise hundreds of billions of different sequence possibilities. In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which may or may not be capable of functioning in the manner suggested by the specification. Therefore, the claims fail to meet the written description requirement by encompassing sequences, which are not described in the specification.

6. The rejection of claims 1, 18, 19, 40, 41, 43 and 50-59 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained. Claims 9 and 60 have been cancelled.

Applicants assert that the claims as pending are fully enabled and “[g]iven the guidance and working examples provided by Applicants..., one of ordinary skill in the art would need only routine experimentation ...to practice the full scope of the invention as now claimed.” Applicants’ points of view and arguments have been carefully considered, but found unpersuasive.

Art Unit: 1642

Applicants' claims continue to embrace complements which are to be placed in vectors and host cells; arbitrary antisense nucleic acid sequences which are to reduce the expression of a nucleic acid, SEQ ID NO: 38 and SEQ ID NO: 43; and a kit for detecting the presence of expression of a nucleic acid with a nucleic acid segment. Foremost it is highly unlikely that a complement, which may be a short segment of nucleic acids, is capable of encoding any polypeptide. Any antisense nucleic acid sequence that simply binds a nucleic acid molecule is not equivalent to reducing expression of a nucleic acid. There is no assurance that an unspecified nucleic acid sequence is capable of resulting in the reduction of nucleic acid expression. And the kit including a nucleic acid is going to detect a nucleic acid and not a protein. There continues to be a dearth of information regarding the structure and characterization of these claimed complements and antisense nucleic acid sequences in regards to their applicability to producing polypeptides and reducing nucleic acid expression, respectively. Lastly, Applicants claims reading on detection of a protein with a nucleic acid, which is not commensurate with the specification, see Example 2, page 48-53. There is lack of instruction in the specification enabling one skilled in the art to make and practice the invention commensurate in scope of the claims.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 41 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 41 lacks antecedent bases for "the portion" found on line 6 of the claim.

Claim Rejections - 35 USC § 102

9. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by 1997/1998 Stratagene catalog (page 118, 1997/1998). The 1997/1998 Stratagene catalog discloses the Prime-It II Random Primer Labeling Kit containing an instruction manual and hexanucleotides containing all possible 6-nucleotide sequences and would be a complement of nucleic acid molecules that encode polypeptides of greater than 95% identity with SEQ ID NO: 39 or SEQ ID NO: 44.

10. The rejection of claim 1 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,880,102 (filed January 17, 1995) is maintained. Claim 9 has been cancelled. Sequence 1 of U.S. Patent #5,880,102 continues to disclose nucleic acid molecules which would be considered complements of nucleic acid molecules that encode polypeptides of greater than 95% identity with SEQ ID NO: 39 or SEQ ID NO: 44.

Allowable Subject Matter


11. Claim 8 is allowed.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she normally can be reached between the hours of 6:30 am to 5:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Alana M. Harris, Ph.D.
18 November 2004

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER
11/29/2004